

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and these remarks.

Claims 12-26 are cancelled presently, and claims 1, 2 and 7 are amended. Upon entry of this response, therefore, claims 1-11 will be pending.

The claims have been amended to address the stated grounds for the objections detailed on page 2 of the action. Based on these corrections, Applicant requests that the Examiner withdraw the objections.

Also on page 2, the Examiner has asked for a "new abstract ... presented on a separate sheet, apart from any other text." This Applicant has done (see below).

In addition, the claims have been revised to prescribe that the venous blood is peripheral venous blood. This change is well-supported in the specification, e.g., page 12 at line 28 *ff.* ("Case 1"), page 13 at line 12 *ff.* ("Case 2"), and at page 13, line 33 *ff.* ("Case 4"). Accordingly, no new matter is added.

On pages 3-5 of the action, the Examiner elaborates on a rationale for rejecting the claims for alleged lack of novelty over the 2001 article by BEGELEISEN, entitled "Models of Venous Admixture." In this regard, however, Applicant notes that Begeleisen's equation "(2)" is a mass conservation equation, which says that the mass of oxygen in the venous plus that in the lung capillaries equals that in the artery. This equation is standard in respiratory physiology and describes the transport of oxygen over the lungs.

To the contrary, the present claims recite that the venous blood sample is a peripheral blood sample. Accordingly, the claimed invention relates to oxygen transport over the tissues and not the lungs.

More particularly, in Begeleisen's equation (2) the variable $Cv(\bar{v})O_2$ represents the oxygen concentration in the mixed venous blood, the bar over the "v" (subscript) reflecting standard nomenclature to this end. This concentration can be measured only if one places a catheter through the heart into the pulmonary circulation, a very invasive procedure, which is performed solely on the most ill of patients. Begeleisen points this out on page 161, left column: "the use of equation 3 is impractical in routine clinical care because the mixed venous blood is rarely sampled". In patients where it is

sampled, one invariably has to place a catheter in the artery, because this is much less invasive than is a catheter through the heart. An arterial catheter gives direct measurement of arterial blood, which renders wholly redundant the use of equation (2) to calculate arterial values.

In Applicant's claimed method, only peripheral venous blood is required, not arterial blood. beginning at page 12, "Part 3" of the application validates measurements taken with peripheral venous blood, an endeavor that is not possible with the equations presented by Bigeleison.

The Bigeleisen article is directed to describing how the pulmonary shunt fraction (or venous admixture) is estimated, and so there is no teaching of a methodology for converting venous blood values to arterial values, as presently claimed. In particular, Bigeleisen does not describe the use of his equations to calculate arterial blood. Rather, his equation 2 is reformatted into equation 3, whereby measurements of both arterial and venous blood are used to calculate the shunt fraction.

By the same token, Bigeleisen's "equation 3A" (page 161, right column), while referencing the respiratory quotient, cannot be used to calculate arterial values from venous values. Equation 3A represents the relationship between arterial (a) and alveolar (A) PO₂, without reference to the venous oxygen level.

Figure 3 of the Bigeleisen article also cannot be used to calculate arterial values from venous. It represents the relationship between arterial (a) and alveolar (A) PO₂, in a form whereby Bigeleisen explicitly indicates that the mixed venous oxygen concentration is assumed constant (see page 161, left column).

CONCLUSION

Applicant submits, therefore, that present claims are patentable over the prior art illustrated by Bigeleisen. Applicant further submits, therefore, that this application is in allowable condition, and an early indication to this effect is requested. Examiner Sujoy is invited to contact the undersigned directly, should she feel than any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account.

If any extension is needed for timely acceptance of submitted papers, then Applicant hereby petitions for such extension under 37 CFR §1.136 and authorizes payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

Date 5 December 2007

By S.A. Bent

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768